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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,182	08/07/2003	Christopher A. Thierfelder	AMS-161	1760

7590 04/07/2006

Attention: Jeffrey J. Hohenshell
AMS Research Corporation
10700 Bren Road West
Minnetonka, MN 55343

EXAMINER	
GILBERT, ANDREW M	
ART UNIT	**PAPER NUMBER**
3767	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/636,182	THIERFELDER ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-12,14,17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/8/06, 2/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. In response to the restriction requirement claims 1-18 are pending and claims 19-20 are cancelled as requested in the "Response to Restriction Requirement" reply filed 3/3/06.

2. Claims 1-12, 14, 17, and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/3/2006.

3. The Applicant elected Species I: Figs 1-3 of the implantable drug delivery device species and Species IV: Storage and delivery means for a substance that resists fibrous occlusions of the drug delivery port of the delivery path preservation species. Claims 2, 9, and 13-18 are readable thereon; however, claims 2 and 9 are further withdrawn as being dependent upon withdrawn claims drawn to a nonelected species. Furthermore, claims 14, 17, and 18 are withdrawn as being drawn to a nonelected species of delivery path preservation means. The Applicant elected the delivery path preservation means to be Species IV: Storage and delivery means for a substance that resists fibrous occlusions of the drug delivery port which is a patentably distinct species from the nonelected delivery path preservation means species being poly(glycine-valine-glycine-valine-proline) associated with the catheter, or a fluid or films coating on the catheter.

4. The Examiner agrees with the Applicant that independent claims 1, 3, and 13 are generic to Species I of the implantable drug delivery device species and that claim 13 is

generic to Species IV of the delivery path preservation species. Thus, independent claim 13 is generic to both Species I and IV.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 3/9/06 and 2/2/2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

6. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract

on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

7. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Implantable drug delivery device for treating erectile dysfunction.

Claim Notes

8. In reference to claim 13, the Examiner notes that the Applicant has invoked 35 U.S.C. 112 6th paragraph by using "means for" language reciting function, and not reciting sufficient structure of the means referred to in the specification.

9. In reference to claim 16, the Examiner notes that the Applicant has appeared to invoke 35 U.S.C. 112 6th paragraph by using "means for" language, reciting function, and not reciting sufficient structure of the means referred to in the specification.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 13, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Rise et al (5752930). Rise et al discloses an implantable drug delivery system (10) having a storage means (19) for storing a drug; a metering means for metering a predetermined, effective amount of the drug through valves (101, 102), electronic module (32), batteries (34, 36), and a pump system (44) (col 4, lns 9-14; col 8, lns 5-24); a delivery means (44) for delivering an effective amount of drug comprising a catheter (22) having a longitudinal axis (Fig 2) and having a plurality of drug delivery ports (172, Fig 16) being a plurality of slits (172, Fig 16) that are movable between an open position to delivery the drug to the patient and a closed position (col 1, lns 48-54; col 6, lns 38-48); a drug delivery path preservation means for resisting fibrous occlusion of the drug delivery ports comprising a means for delivering a substance (col 3, lns 6-13) that is capable of resisting fibrous occlusions through the drug delivery ports.

12. Claims 13, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Heil, Jr. (5041107). Heil, Jr. discloses an implantable drug delivery system (10) having a storage means (14; col 5, lns 29-38) for storing a drug; a metering means for metering a predetermined, effective amount of the drug though a drive electrode (22), a power source (12) and oppositely charged return electrode (26) (col 2, lns 8-56; col 4, lns 16-30); a delivery means for delivering an effective amount of drug comprising a catheter (14) having a longitudinal axis (Fig 1) and having a plurality of drug delivery ports (22, 32, 44) being a plurality of slits (22, 32, 44) that are movable between an open position to delivery the drug to the patient and a closed position (col 3, lns 54-56; col 4, lns 7-9; col 4, lns 16-30); a drug delivery path preservation means for resisting

fibrous occlusion of the drug delivery ports comprising a means for delivering a substance (col 1, ln 65-col 2, ln 5; col 4, lns 6-13) that is capable of resisting fibrous occlusions through the drug delivery ports.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Santini, Jr. et al (6491666) teaches an implantable drug delivery device with microchip drug reservoirs and microchannels; Ito et al (5019393) teaches biocompatible substances for thromboresistance; Rosenberg (5630843) teaches infusion solutions for inhibiting fibrosis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571)272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew Gilbert

KEVIN SIRMONS
PRIMARY EXAMINER